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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,453	02/28/2002	Lingju Cao	219425US0	4985
22850	7590	09/22/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			TRAN, THAO T	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/084,453	Applicant(s) CAO ET AL.	
	Examiner Thao T. Tran	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Upon further consideration, the Restriction requirement presented in the Office action of June 24, 2004 has been withdrawn.
2. Claims 1-12 and 14-21 are currently pending in this application. Claim 13 has been canceled.

### ***Claim Objections***

3. Claim 9 is objected to because of the following informalities: it is preferred to change "obtainable", line 2, to --obtained--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. Claims 10-12, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite because the claim is directed to a product; however, the claim does not convey what the product comprises. Instead, the claim recites a method of producing the product. Applicants are required to recite positive limitations for the product.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, 8-12, and 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Margolin et al. (US Pat. 6,359,118).

Margolin teaches crosslinked enzyme (glycoprotein) aggregates (crystals) and a method of preparing (see abstract); the method comprising providing a plurality of enzyme molecules (glucose oxidase); aggregating the enzyme molecules by a precipitating agent (polyethylene glycol) (see col. 17, ln. 51-52; Example 2); crosslinking the aggregated enzyme molecules to one another with a crosslinking agent (see col. 9, ln. 1-10).

In regards to claims 1-6, 9-12, Margolin teaches the crosslinking agent to be a combination of glutaraldehyde and a diaminoalkane (diaminooctane) (see col. 25, ln. 67, bridging col. 26, ln. 3).

In regards to claim 8, Margolin teaches the enzymes to be lipase, esterase, or protease (see col. 8, ln. 28-34).

In regards to claim 17, Margolin teaches the use of the crosslinking agent to crosslink a protein molecule to another protein molecule (see col. 5, ln. 35-37).

Art Unit: 1711

In regards to claims 18-21, Margolin further teaches the enzyme crystals being combined with solid carrier materials (see col. 11, ln. 5-6, 25-26; col. 12, ln. 16-17). Although Margolin is silent with respect to the enzyme crystals being crosslinked with the carrier, since Margolin teaches the same enzyme crystals with the same crosslinking agent to the presently claimed invention, the reference's enzyme crystals would inherently be crosslinked to the carrier.

***Allowable Subject Matter***

7. Claims 7 and 14-16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: no prior art has been found to teach, disclose, or fairly suggest a method of making crosslinked enzyme aggregates, the method comprising providing a crosslinking agent, wherein the crosslinking agent is prepared by combining a second compound and a first compound in a molar ratio of 10-1:1; in combination with all of the other limitations of claim 1.

***Response to Arguments***

9. Applicant's arguments filed July 26, 2004 have been fully considered but they are not persuasive.

Throughout the Remarks, Applicants contend that in the presently claimed invention, the crosslinker is used as a spacer between enzyme molecules to form enzyme aggregates, whereas in the invention of Margolis, the enzyme crystals are obtained by crosslinking the crystals

Art Unit: 1711

through one or more carbohydrate moieties on or through the amino acid side chain in the glycoprotein. However, the claim language does not include the use of the crosslinker as a spacer or the specific crosslinking in order to differentiate the presently claimed invention from the prior art. Thus, what Margolis teaches would read on the instant claims.

As pointed out by Applicants on page 8, 1<sup>st</sup> paragraph, of the Remarks and in paragraph 8 above, by choosing the proper ratio between the first and second compounds, a crosslinking agent would have the required length and thus spacing properties, to be patentably distinguish from the prior art.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1711

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 8:30 a.m. - 5:00 p.m..

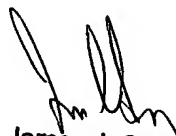
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 20, 2004

  
James J. Seidleck  
Supervisory Patent Examiner  
Technology Center 1700